

JUN 29 2001

NOTE TO STUDY FILE

Study No: 8450
Sponsor: Philip Morris
Protocol No: PM-8450

Accession D517733 (PAB 078) was sent in with an aliquot that had the final number obliterated so the aliquot read 07. The aliquot was labeled SR2075 and was for nicotine and nicotine metabolite. It can not be assured that is sample belonged to subject PAB. It was determined on the conference call on June 26, 2001, that this sample would be discarded. This subject was not randomized to go to INBIFO/TX. There will be enough samples.

Container 38 for accession number D518893 (PMB, 048) was inadvertently thawed. The aliquot was for Malondialdehyde blood and was to be sent to TX. This subject was not randomized to be analyzed by TX. This sample will be discarded per discussion on the conference call on June 26, 2001.

Accessions number 060501A was a container of cigarette filters that was only labeled with the collection dates and time (June 1-4 at 1100). Upon review of the data and the appointment schedule, there was only one subject that came in on June 4. This subject is a smoker and it was reasonably deduced that this specimen belongs to subject 069. Covance CCLS has been authorized by Philip Morris to re-label this specimen and ship it to INBIFO. Georg will discuss with his QA department.

Russell Dixon, M.D.
Principal Investigator

Date

Mary Larson, RN, CCRC
Senior Project Manager

Date

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